

**RESPONSE UNDER RULE 312  
EXPEDITED HANDLING PROCEDURES**

In re Patent Application of

Atty Dkt. 1579-312

NAIR et al

C# M#

Serial No. 09/171,916

C/A.U.

1636

Filed: February 16, 1999

Examiner: Guzo, D.

Date: July 18, 2005

Title: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNA**Mail Stop Issue Fee**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**REQUEST UNDER RULE 312**

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

**☒ Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

Total effective claims after amendment 0 minus highest number  
previously paid for 20 (at least 20) = 0 x \$50.00 \$0.00 (1202)/\$0.00 (2202) \$

Independent claims after amendment 0 minus highest number  
previously paid for 3 (at least 3) = 0 x \$200.00 \$0.00 (1201)/\$0.00 (2201) \$

If proper multiple dependent claims now added for first time, (ignore improper); add  
\$360.00 (1051)/\$180.00 (2051) \$

Petition is hereby made to extend the current due date so as to cover the filing date of this  
paper and attachment(s)

One Month Extension \$120.00 (1251)/\$60.00 (2251)  
Two Month Extensions \$450.00 (1252)/\$225.00 (2252)  
Three Month Extensions \$1020.00 (1253)/\$510.00 (2253)  
Four Month Extensions \$1590.00 (1254)/\$795.00 (2254) \$

Terminal disclaimer enclosed, add \$130.00 (1814)/ \$65.00 (2814) \$

☐ Applicant claims "small entity" status. ☐ Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee \$180.00 (1806) \$

Assignment Recording Fee \$40.00 (8021) \$

Other: \$

**TOTAL FEE ENCLOSED \$ 0.00**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

901 North Glebe Road, 11th Floor  
Arlington, Virginia 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100  
MJW:tat

NIXON & VANDERHYTE P.C.  
By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

Allowed: July 7, 2005

HAIR et al

Atty. Ref.: 1579-312; Confirmation No. 8645

JUL 18 2005 Appl. No. 09/171,916

TC/A.U. 1636

Filed: February 16, 1999

Examiner: Guzo, D.

For: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNA

\* \* \* \* \*

July 18, 2005

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

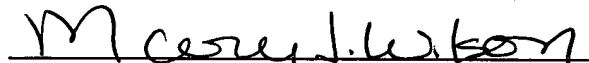
**REQUEST UNDER RULE 312**

The Examiner is requested to initial and return the PTO-1449 Forms submitted with Information Disclosure Statements filed in the above on April 30, 2004, May 3, 2004, May 5, 2004 (see attached copy of postcard receipts evidencing these filing) and April 18, 2005 (copy of facsimile transmission receipt evidencing this filing is attached). Further copies of these Information Disclosure Statements are attached.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By:

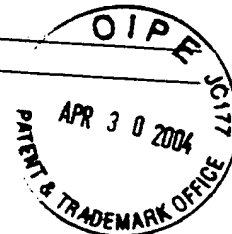
  
Mary J. Wilson  
Reg. No. 32,955

MJW:tat  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100



Serial No.: 09/171,916  
Applicant: NAIR et al  
Title: METHODS FOR TREATING  
CANCERS AND PATHOGENS  
Atty: MJW  
Date: 4-30-2004  
Client: DUKE UNIV.  
Ref: 1579-312

\_\_\_\_ Amendment  
\_\_\_\_ Pages Specification  
\_\_\_\_ Claims  
\_\_\_\_ Sheets Drawings: Formal \_\_\_\_\_  
Informal \_\_\_\_\_  
\_\_\_\_ Declaration (\_\_\_\_\_ Pages)  
\_\_\_\_ Assignment  
\_\_\_\_ Priority Document  
\_\_\_\_ Base Issue Fee Transmittal  
\_\_\_\_ Fee (Check)



Other: IDS w/PTO-1449 FORM (IN DUPL) +  
REFS.

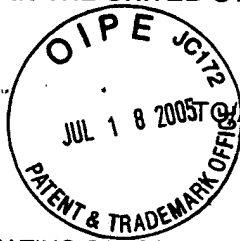
## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

NAIR et al

Serial No. 09/171,916

Filed: February 16, 1999

Title: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNA

Atty Dkt. 1579-312

C# M#

1636

Examiner: Guzo, D.

Date: April 30, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☐ **Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

Total effective claims after amendment	0	minus highest number		
previously paid for	20	(at least 20) =	0 x \$ 18.00	\$ 0.00

Independent claims after amendment	0	minus highest number		
previously paid for	3	(at least 3) =	0 x \$ 86.00	\$ 0.00

If proper multiple dependent claims now added for first time, add \$290.00 (ignore improper)	\$ 0.00
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Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$420.00/2 months; \$950.00/3 months)	\$ 0.00
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T. nal disclaimer enclosed, add \$ 110.00	\$ 0.00
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<input type="checkbox"/> First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$770.00)	\$ 0.00
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☐ Please enter the previously unentered, filed

☐ Submission attached

<b>Subtotal</b>	<b>\$ 0.00</b>
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If "small entity," then enter half (1/2) of subtotal and subtract	-\$ 0.00
<input type="checkbox"/> Applicant claims "small entity" status. <input type="checkbox"/> Statement filed herewith	

Rule 56 Information Disclosure Statement Filing Fee (\$180.00)	\$ 0.00
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Assignment Recording Fee (\$40.00)	\$ 0.00
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Other:	0.00
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<b>TOTAL FEE ENCLOSED</b>	<b>\$ 0.00</b>
---------------------------	----------------

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1100 North Glebe Road, 8<sup>th</sup> Floor  
Arlington, Virginia 22201-4714  
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Facsimile: (703) 816-4100  
MJW:tat

NIXON & VANDERHYE P.C.  
By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: \_\_\_\_\_

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

NAIR et al

Serial No. 09/171,916

Filed: February 16, 1999



Confirmation No. 8645

Atty. Ref.: 1579-312

Group: 1636

Examiner: Guzo, D.

For: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNA

\* \* \* \* \*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

April 30, 2004

Sir:

**INFORMATION DISCLOSURE STATEMENT**

- ☒ 1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**  
[within 3 months of filing or prior to 1st Office Action on the merits]  
N/C
- ☐ 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)]  
N/C
- ☐ 2.(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)]  
\$180.00
- ☐ 3. **Pursuant to 37 CFR 1.97(d)**  
[after Final Office Action or Allowance (requires Rule 97(e)  
Statement and Rule 17(p) fee), but before final fee payment]  
\$180.00

The following are submitted in the above-identified application in compliance with  
37 C.F.R. §§ 1.97 and 1.98:

- ☒ 4. A list of documents on Form PTO-1449 together with copies of each  
identified document and a translation or a concise explanation of  
each non-English language document (such as a Search Report) is  
enclosed herewith.

This paper is submitted in accordance with:

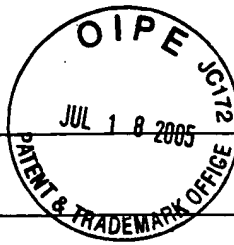
- ☒ 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- ☐ 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
  - ☐ a) The required Statement made in item 8 below; or
  - ☐ b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- ☐ 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
  - ☐ a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
  - ☐ b) The required Statement is stated in item 8 below.
- ☐ 8. Statement under 37 CFR 1.97(e)
  - ☐ a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
  - ☐ b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
- ☒ 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

NAIR et al  
Serial No. 09/171,916  
April 30, 2004

Respectfully submitted,  
NIXON & VANDERHYE P.C.

By: Mary J. Wilson  
Mary J. Wilson  
Reg. No. 32,955

1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100


**INFORMATION DISCLOSURE  
CITATION**

ATTY. DOCKET NO.

1579-312

APPLICANT

NAIR et al

FILING DATE

February 16, 1999

SERIAL NO.

09/171,916

GROUP

1636

(Use several sheets if necessary)

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,670,186	12/2003	Nair et al			

**FOREIGN PATENT DOCUMENTS**

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
WO 95/34638	12/1995	WIPO			

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

	Celluzzi et al, "Peptide-pulsed Dendritic Cells Induce Antigen-specific, CTL-mediated Protective Tumor Immunity", J. Exp. Med. 183:283-287 (1996)
	Kormanec and Farkasovsky, "Isolation of total RNA from yeast and bacteria and detection of rRNA in northern blots", Biotechniques 17(5):838-842 (1994) - Pub Med - PMID: 7530979
	Porter et al, "A rapid membrane-based viral RNA isolation method for the polymerase chain reaction", Nucleic Acids Research 19(14):4011 (1991)

*Examiner	Date Considered
-----------	-----------------

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)





Serial No.: 09/171,916  
Applicant: NAIR et al  
Title: METHODS FOR TREATING  
CANCERS AND PATHOGENS.

Atty: MJW  
Date: 5-3-2004  
Client: DUKE UNIV  
Ref: 1579-312

\_\_\_\_ Amendment  
\_\_\_\_ Pages Specification  
\_\_\_\_ Claims  
\_\_\_\_ Sheets Drawings: Formal \_\_\_\_\_  
Informal \_\_\_\_\_  
\_\_\_\_ Declaration (\_\_\_\_\_ Pages)  
\_\_\_\_ Assignment  
\_\_\_\_ Priority Document  
\_\_\_\_ Base Issue Fee Transmittal  
\_\_\_\_ Fee (Check)



Other: IDS w/PTD-1449 FORM (IN DUPL.) +  
REF. + CO-PENDING APPLN CLAIMS

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty Dkt. 1579-312

NAIR et al

C# M#

Serial No. 09/171,916

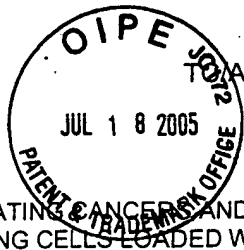
T/A.U.

1636

Filed: February 16, 1999

Examiner: Guzo, D.

Date: May 3, 2004

Title: METHODS FOR TREATING CANCER AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNACommissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

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Terminal disclaimer enclosed, add \$ 110.00 \$ 0.00

☐ First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$770.00) \$ 0.00

☐ Please enter the previously unentered, filed

☐ Submission attached

**Subtotal \$ 0.00**

If "small entity," then enter half (1/2) of subtotal and subtract -\$ 0.00

☐ Applicant claims "small entity" status. ☐ Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee (\$180.00) \$ 0.00

Assignment Recording Fee (\$40.00) \$ 0.00

Other: 0.00

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1100 North Glebe Road, 8<sup>th</sup> Floor  
Arlington, Virginia 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100  
MJW:tat

NIXON &amp; VANDERHYE P.C.

By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

NAIR et al

Serial No. 09/171,916

Filed: February 16, 1999



Confirmation No. 8645

Atty. Ref.: 1579-312

Group: 1636

Examiner: Guzo, D.

For: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNA

\* \* \* \* \*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

May 3, 2004

Sir:

**INFORMATION DISCLOSURE STATEMENT**

- ☒ 1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**  
[within 3 months of filing or prior to 1st Office Action on the merits]  
N/C
- ☐ 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)]  
N/C
- ☐ 2.(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
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\$180.00
- ☐ 3. **Pursuant to 37 CFR 1.97(d)**  
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\$180.00

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identified document and a translation or a concise explanation of  
each non-English language document (such as a Search Report) is  
enclosed herewith.

This paper is submitted in accordance with:

- ☒ 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- ☐ 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
- ☐ a) The required Statement made in item 8 below; or
- ☐ b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- ☐ 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
- ☐ a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
- ☐ b) The required Statement is stated in item 8 below.
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- ☐ a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
- ☐ b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
- ☒ 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

NAIR et al  
Serial No. 09/171,916  
May 3, 2004

The Examiner's attention is directed to the existence of co-pending Application No. 09/875,264. A copy of the claims of Appln. No. 09/875,264 is attached.

Respectfully submitted,  
NIXON & VANDERHYE P.C.

By: Mary J. Wilson  
Mary J. Wilson  
Reg. No. 32,955

1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100

1636

U.S. PATENT DOCUMENTS

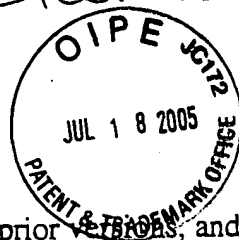
[illegible][illegible][illegible]

Date Considered

Form PTO-FB-A820 (Also PTO-1449)

FAIR et al  
Appl. No. 09/875,264  
July 28, 2003

Claims of Appln No  
09/875,264



**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-18 (Cancelled).

19. (Currently Amended) A method for producing a cytotoxic T lymphocyte (CTL), said method comprising:

(i) providing a T lymphocyte;

(ii) contacting said T lymphocyte *in vitro* with the an RNA-loaded APC of

claim 14 antigen presenting cell (APC) produced by a method comprising:

introducing into an APC *in vitro* RNA selected from the group consisting of tumor-derived RNA comprising tumor-specific RNA and pathogen-derived RNA comprising pathogen specific RNA, thereby producing said RNA-loaded APC; and

maintaining said T lymphocyte under conditions conducive to CTL proliferation, thereby producing a CTL.

20-38 (Cancelled).

39. (New) A method of producing cytotoxic T lymphocytes (CTL), said method comprising:

(i) introducing RNA encoding an antigen into antigen-presenting cells (APC) *in vitro*, wherein said RNA is tumor-derived or pathogen-derived, thereby producing APC that functionally present said antigen on the surface thereof,

(ii) contacting the APC produced in step (i) with lymphocytes *in vitro*, wherein the lymphocytes comprise CTL, thereby producing CTL that recognize said antigen; and

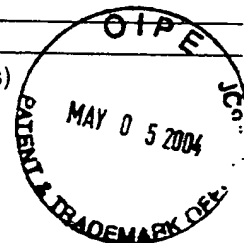
(iii) maintaining the CTL produced in step (ii) in culture.





Serial No.: 09/171,914  
Applicant: NAIR et al  
Title: METHODS FOR TREATING  
CANCELS AND PATHOGEN INFECTIONS...  
Atty: M. W.  
Date: 5-5-2004  
Client: DUKE UNIV  
Ref: 1579-312

\_\_\_\_ Amendment  
\_\_\_\_ Pages Specification  
\_\_\_\_ Claims  
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Informal \_\_\_\_\_  
\_\_\_\_ Declaration ( \_\_\_\_\_ Pages)  
\_\_\_\_ Assignment  
\_\_\_\_ Priority Document  
\_\_\_\_ Base Issue Fee Transmittal  
\_\_\_\_ Fee (Check)



Other: SUPPLEMENTAL IDS w/ PTD-1449 FORM  
+ REF.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty Dkt. 1579-312

C# M#

NAIR et al

TO A.U.

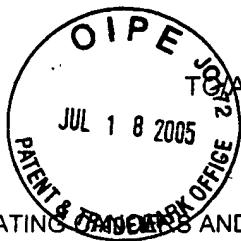
1636

Serial No. 09/171,916

Examiner: Guzo, D.

Filed: February 16, 1999

Date: May 5, 2004

Title: METHODS FOR TREATING TUBERCULOSIS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNA

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

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MJW:tat

NIXON &amp; VANDERHYE P.C.

By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

NAIR et al

Serial No. 09/171,916

Filed: February 16, 1999

For: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNA



Confirmation No. 8645

Atty. Ref.: 1579-312

Group: 1636

Examiner: Guzo, D.

\* \* \* \* \*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

May 5, 2004

Sir:

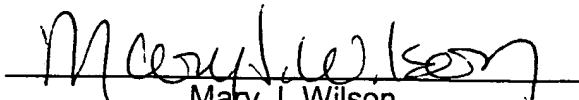
**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Supplemental to the Information Disclosure Statement filed April 30, 2004, attached is a full text copy of the Kormanec and Farkasovsky article ("Isolation of total RNA from yeast and bacteria and detection of rRNA in northern blots", Biotechniques 17(5):838-842 (1994)). Also attached is a further PTO-1449 which the Examiner is requested to initial and return same.

No fee is believed to be necessary, however, should the Office take a different view, please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

NAIR et al  
Serial No. 09/171,916  
May 5, 2004

Respectfully submitted,  
NIXON & VANDERHYE P.C.

By:   
Mary J. Wilson  
Regy No. 32,955

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Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
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**INFORMATION DISCLOSURE  
CITATION**

ATTY. DOCKET NO.

1579-312

APPLICANT

NAIR et al

FILING DATE

February 16, 1999

SERIAL NO.

09/171,916

GROUP

1636

(Use several sheets if necessary)

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

**FOREIGN PATENT DOCUMENTS**

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

	Kormanec and Farkasovsky, "Isolation of total RNA from yeast and bacteria and detection of rRNA in northern blots", Biotechniques 17(5):838-842 (1994)

*Examiner	Date Considered
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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)



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NIXON & VANDERTHY PC Fax: 703-816-4100		Apr 18 2005 20:02 P.01	
<b>Nixon &amp; Vandertye PC</b> ATTORNEY AT LAW			
8TH FLOOR 1100 NORTH GLEBE ROAD ARLINGTON, VIRGINIA 22201-4714		TELEPHONE: (703) 816-4000 FACSIMILE: (703) 816-4100 WRITER'S DIRECT DIAL NUMBER: (703) 816-4011	
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Atty Dkt.:	1579-312	Date:	April 18, 2005
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<b>ATTACHMENT/S: OFFICIAL AMENDMENT W/PTO-1449 FORM, REFERENCE AND TERMINAL DISCLAIMER</b>			
<b>MESSAGE:</b>			
In re PATENT APPLICATION OF:			
NAIR et al			
Serial No.: 09/171,918			
Filed: February 16, 1999			
For: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING ANTIGEN-PRESENTING CELLS LOADED WITH RNA			
<b>CONFIDENTIALITY NOTE</b> The documents accompanying this facsimile transmission contain information belonging to Nixon & Vandertye, which is confidential and/or legally privileged. This information is only intended for the use of the individual or entity named above. IF YOU ARE NOT THE NAMED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISCLOSURE, COPYING, DISTRIBUTION OR TAKING OF THIS INFORMATION FOR ANY USE WHATSOEVER IS STRICTLY PROHIBITED. If you have received this facsimile in error, please immediately contact us by telephone to arrange for return of the original documents to us.			
PAGE 1/22 * RCVD AT 4/18/2005 8:02:42 PM [Eastern Daylight Time] * SVR:USPTO-EF706-12 * DMS:8728306 * CSID:703 816 4100 * DURATION (min-sec):07:34 846556			



**Nixon & Vanderhye P.C.**  
ATTORNEY AT LAW

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Atty Dkt.: 1579-312 Date: April 18, 2005

To: Examiner Guzo, D. - Group: 1636  
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Tabitha A. Trice  
**FACSIMILE OPERATOR**

**CERTIFICATION OF FACSIMILE TRANSMISSION**

I hereby certify that this paper and any noted attachments are being facsimile transmitted to the Patent and Trademark Office on April 18, 2005.

Mary J. Wilson  
Mary J. Wilson

**ATTACHMENT/S: OFFICIAL AMENDMENT W/PTO-1449 FORM, REFERENCE  
AND TERMINAL DISCLAIMER**

**MESSAGE:**

In re PATENT APPLICATION OF:

NAIR et al  
Serial No.: 09/171,916  
Filed: February 16, 1999  
For: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS  
USING ANTIGEN-PRESENTING CELLS LOADED WITH RNA

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty Dkt. 1579-312

C# M#

NAIR et al

TC/A.U. 1636

Serial No. 09/171,916

Examiner: Guzo, D.

Filed: February 16, 1999

Date: April 18, 2005

Title: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNA



Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE/AMENDMENT/LETTER**

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☐ **Correspondence Address Indication Form Attached.**

**Fees are attached as calculated below:**

Total effective claims after amendment	0	minus highest number	
previously paid for	20	(at least 20) =	0 x \$50.00 \$0.00 (1202)/\$0.00 (2202) \$

Independent claims after amendment	0	minus highest number	
previously paid for	3	(at least 3) =	0 x \$200.00 \$0.00 (1201)/\$0.00 (2201) \$

If proper multiple dependent claims now added for first time, (ignore improper); add  
\$360.00 (1051)/\$180.00 (2051) \$

Petition is hereby made to extend the current due date so as to cover the filing date of this  
paper and attachment(s)

One Month Extension	\$120.00 (1251)/\$60.00 (2251)
Two Month Extensions	\$450.00 (1252)/\$225.00 (2252)
Three Month Extensions	\$1020.00 (1253)/\$510.00 (2253)
Four Month Extensions	\$1590.00 (1254)/\$795.00 (2254) \$ 225.00

Terminal disclaimer enclosed, add \$130.00 (1814)/\$65.00 (2814) \$ 65.00

☐ Applicant claims "small entity" status. ☐ Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee \$180.00 (1806) \$

Assignment Recording Fee \$40.00 (8021) \$

Other: \$

**TOTAL FEE TO BE DEBITED \$ 290.00**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

1100 North Glebe Road, 8<sup>th</sup> Floor  
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Facsimile: (703) 816-4100  
MJW:tat

NIXON & VANDERHYE P.C.  
By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty Dkt. 1579-312

C# M#

NAIR et al

TC/A.U.

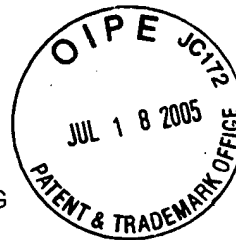
1636

Serial No. 09/171,916

Examiner: Guzo, D.

Filed: February 16, 1999

Date: April 18, 2005

Title: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNACommissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE/AMENDMENT/LETTER**

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previously paid for	20	(at least 20) =	0 x \$50.00
			\$0.00 (1202)/\$0.00 (2202) \$

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previously paid for	3	(at least 3) =	0 x \$200.00
			\$0.00 (1201)/\$0.00 (2201) \$

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\$180.00 (1806) \$

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\$40.00 (8021) \$

Other:

\$

**TOTAL FEE TO BE DEBITED \$ 290.00**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON &amp; VANDERHYE P.C.

By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

NAIR et al

Atty. Ref.: 1579-312; Confirmation No. 8645

Appl. No. 09/171,916

TC/A.U. 1636

Filed: February 16, 1999

Examiner: Guzo, D.

For: METHODS FOR TREATING CANCERS AND PATHOGEN INFECTIONS USING  
ANTIGEN-PRESENTING CELLS LOADED WITH RNA

\* \* \* \* \*

April 18, 2005

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**AMENDMENT**

This is in response to the Office Action dated November 17, 2004, in the above matter, the period for response having been extended up to April 17, 2005, by submission of the required petition and fee herewith. Kindly amend the above-identified application as follows:

**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Previously Presented) A method for producing an RNA-loaded antigen presenting cell (APC) that presents on its surface a tumor antigenic epitope encoded by RNA of a tumor, wherein the epitope induces T cell proliferation, said method comprising:

introducing into an antigen-presenting cell *in vitro* RNA of a tumor comprising tumor-specific RNA that encodes an antigen that induces T cell proliferation and tumor immunity, thereby producing an RNA-loaded APC that presents on its surface a tumor antigenic epitope encoded by the RNA of the tumor, wherein the epitope induces T cell proliferation.

2. (Original) The method of claim 1, wherein said APC is a dendritic cell.

3. (Original) The method of claim 1, wherein said APC is a macrophage.

4. (Original) The method of claim 1, wherein said APC is an endothelial cell.

5. (Original) The method of claim 1, wherein said APC is an artificially generated APC.

6. (Previously Presented) The method of claim 1, wherein said RNA comprises poly A<sup>+</sup> RNA.

7. (Previously Presented) The method of claim 1, wherein said RNA comprises cytoplasmic RNA.

8. (Original) The method of claim 1, wherein the RNA is introduced into the APC by contacting the APC with the RNA in the presence of a cationic lipid.
9. (Previously Presented) The method of claim 1, wherein said RNA is provided as a fractionated tumor extract that is fractionated with respect to a non-RNA component of the tumor extract.
10. (Original) The method of claim 1, further comprising introducing into the APC RNA encoding an immunomodulator.
11. (Original) The method of claim 10, wherein the immunomodulator is a cytokine.
12. (Original) The method of claim 10, wherein the immunomodulator is a costimulatory factor.
13. (Currently Amended) The An isolated RNA-loaded APC produced by the method of claim 1.
14. (Previously Presented) A method for treating a tumor in a patient, said method comprising  
administering to the patient a therapeutically effective amount of the RNA-loaded APC of claim 13.

15. (Previously Presented) The method of claim 14, wherein the RNA is obtained from said patient.

16. (Previously Presented) The method of claim 1, wherein the RNA is obtained from fixed tissue.

17. (Previously Presented) The method of claim 14, wherein the RNA is obtained from a donor patient.

18. (Original) A method for producing a cytotoxic T lymphocyte that is cytotoxic for a cell which presents a tumor antigen (CTL), said method comprising:

providing a T lymphocyte;

contacting said T lymphocyte *in vitro* with the RNA-loaded APC of claim 13; and

maintaining said T lymphocyte under conditions conducive to CTL proliferation, thereby producing a CTL that is cytotoxic for a cell which presents a tumor antigen.

19-24 (Cancelled).

25. (Previously Presented) The method of claim 1, wherein the RNA is obtained from a melanoma.

26. (Previously Presented) The method of claim 1, wherein the RNA is obtained from a bladder tumor.

27. (Previously Presented) The method of claim 1, wherein the RNA is obtained from a tumor selected from the group consisting of a breast cancer tumor, a colon cancer tumor, a prostate cancer tumor, and an ovarian cancer tumor.

28. (Cancelled).

29. (Original) The method of claim 1, wherein said RNA is prepared by amplification and *in vitro* transcription.

30. (Previously Presented) The method of claim 1, wherein said RNA comprises nuclear RNA.

31. (Original) The method of claim 1 wherein said RNA comprises a minigene.

32. (Original) The method of claim 1, wherein said RNA is prepared by *in vitro* transcription.

33. (Previously Presented) A method for producing an RNA-loaded antigen presenting cell (APC) that presents on its surface a pathogen antigenic epitope encoded by the RNA, wherein the epitope induces T cell proliferation, said method comprising:

introducing into an antigen-presenting cell *in vitro* RNA of a pathogen consisting essentially of RNA encoding a pathogen antigen that induces T cell proliferation and an immune response to the pathogen, thereby producing an RNA-loaded APC that presents on its surface a

pathogen antigenic epitope encoded by the RNA, wherein the epitope induces T cell proliferation.

34. (Original) The method of claim 33, wherein said APC is selected from the group consisting of dendritic cells, macrophages, and endothelial cells.

35. (Original) The method of claim 33, wherein said APC is an artificially generated APC.

36. (Previously Presented) The method of claim 33, wherein said RNA comprises poly A<sup>+</sup> RNA.

37. (Previously Presented) The method of claim 33, wherein said RNA is obtained from a virus.

38. (Original) The method of claim 37, wherein said virus is selected from the group consisting of Hepatitis viruses, human immunodeficiency viruses, influenza viruses, poliomyelitis viruses, measles viruses, herpes viruses, mumps viruses, and rubella viruses.

39. (Previously Presented) The method of claim 33, wherein said RNA is obtained from a bacterium.

40. (Original) The method of claim 39, wherein said bacterium is selected from the group consisting of *Salmonella*, *Shigella*, and *Enterobacter*.

41. (Previously Presented) A method for producing a cytotoxic T lymphocyte (CTL) that is cytotoxic for a cell which presents a pathogen antigen, said method comprising:

- providing a T lymphocyte;
- contacting said T lymphocyte *in vitro* with the RNA-loaded APC of claim 33; and
- maintaining said T lymphocyte under conditions conducive to CTL proliferation, thereby producing a CTL that is cytotoxic for a cell which presents a pathogen antigen.

42 and 43 (Cancelled).

44. (Previously Presented) The method of claim 18, wherein the RNA comprises at least 80% of polyA+ RNA naturally present in a tumor cell.

45. (Original) The method of claim 44, further comprising detecting sensitization of the contacted T lymphocyte as an indication of the induction of a CTL response.

46. (Original) The method of claim 45, wherein sensitization is detected in a cytotoxicity assay that comprises detecting killing of an RNA-loaded cell that presents on its surface a tumor or pathogen antigenic epitope encoded by RNA.

47. (Original) The method of claim 45, wherein sensitization of the contacted T lymphocyte is detected as an increase in cytokine secretion by the T lymphocyte.



48. (Previously Presented) The method of claim 1, wherein said RNA comprises a sequence that encodes a polypeptide which controls intracellular trafficking of a polypeptide to which it is attached.

49. (Previously Presented) The method of claim 48, wherein said polypeptide that controls intracellular trafficking is KDEL (SEQ ID NO: 1); KFERQ (SEQ ID NO: 2); QREK (SEQ ID NO: 3); MAISGVPVLGFFIIAVLMSAQESWA (SEQ ID NO: 4); a pentapeptide comprising Q flanked on one side by four residues selected from the group consisting of K, R, D, E, F, I, V, and L; or a signal peptide.

50. (Original) The method of claim 33, wherein said RNA comprises a sequence that encodes a trafficking sequence.

51. (Previously Presented) A method for detecting an increase in tumor-specific or pathogen-specific CTL in a patient, the method comprising:

i) contacting a first sample of T lymphocyte from the patient *in vitro* with RNA-loaded APCs that present a cell-surface tumor or pathogen antigenic epitope encoded by the RNA, thereby producing a first expanded sample of T lymphocytes;

ii) administering to the patient the RNA-loaded APCs that present a cell-surface tumor or pathogen antigenic epitope encoded by RNA;

iii) subsequent to the administering step, contacting a second sample of T lymphocytes from the patient *in vitro* with RNA-loaded APCs that present a cell-surface tumor or pathogen antigenic epitope encoded by the RNA, thereby producing a second expanded

sample of T lymphocytes;

iv) comparing sensitization of the first expanded sample of T lymphocytes with sensitization of the second expanded sample of T lymphocytes, wherein an increased level of sensitization in the second sample, as compared with the first sample, is an indicator of an increase in tumor-specific or pathogen-specific CTL.

52. (Original) The method of claim 51, wherein sensitization is measured in a cytotoxicity assay.

53. (Cancel).

54. (Previously Presented) A method for treating a tumor in a patient, said method comprising:

i) producing a cytotoxic T lymphocyte that is cytotoxic for a cell that presents a tumor antigen, said cytotoxic T lymphocyte being produced by a method comprising the steps of:

- a) providing a T lymphocyte;
- b) contacting said T lymphocyte *in vitro* with the RNA-loaded antigen presenting cell of claim 13; and
- c) maintaining said T lymphocyte under conditions conducive to cytotoxic T lymphocyte proliferation, thereby producing said cytotoxic T lymphocyte that is cytotoxic for said cell that presents said tumor antigen, and

ii) administering to said patient a therapeutically effective amount of said cytotoxic T lymphocyte.

55. (Previously Presented) The method of claim 54, wherein the T lymphocyte is obtained from said patient.

56. (Previously Presented) The method of claim 54, wherein the T lymphocyte is obtained from a donor patient.

57. (Previously Presented) The method of claim 54, wherein the RNA is obtained from a tumor of said patient.

58. (Previously Presented) The method of claim 54, wherein the RNA is obtained from a donor patient.

59. (Previously Presented) A method for treating a pathogen infection in a patient, said method comprising:

i) producing a cytotoxic T lymphocyte that is cytotoxic for a cell that presents an antigen of said pathogen, said cytotoxic T lymphocyte being produced by a method comprising the steps of

a) providing a T lymphocyte;

b) contacting said T lymphocyte *in vitro* with the RNA-loaded antigen presenting cell of claim 33; and

- c) maintaining said T lymphocyte under conditions conducive to cytotoxic T lymphocyte proliferation, thereby producing said cytotoxic T lymphocyte that is cytotoxic for a cell that presents said antigen of said pathogen, and
- ii) administering to said patient a therapeutically effective amount of said cytotoxic T lymphocyte.

**REMARKS/ARGUMENTS**

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

The Amendment filed September 7, 2004 includes, in the Remarks, the comment "[a]s regards claim 16 and 53, no teaching of "fixed tissue" is found in the citation". It has now been appreciated that while claim 16 refers to "fixed tissue", claim 53 refers to "frozen tissue". Any confusion resulting from the September 7, 2004 inadvertent misstatement is sincerely regretted. While claim 53 has now been cancelled, that cancellation should not be construed as a disclaimer by Applicants of the subject matter of that claim. While the priority application may not make specific reference to "frozen tissue", one skilled in the art would have appreciated that frozen tissue could be used – in this regard, the Examiner's attention is directed to, for example, the attached abstract of Sugg et al, J. Clin. Endo. Metab. 81:3360 (1996) (which abstract is listed on the accompanying PTO-1449 Form).

Claims 18 and 41 stand rejected as allegedly representing obviousness-type double patenting over claims of Application No. 09/875,264. While in no way agreeing with the Examiner's rejection, a Terminal Disclaimer (and required fee) is submitted herewith merely to advance prosecution.

Claim 13 stands rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Withdrawal of the rejection is submitted to be in order in view of the above-noted claim revision. Reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

NAIR et al  
Appl. No. 09/171,916  
April 18, 2005

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: Mary J. Wilson  
Mary J. Wilson  
Reg. No. 32,955

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Arlington, VA 22201-4714  
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## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

**Atty. Docket No.**

Serial No.

**1579-312**

**09/171,916**

**Applicant**

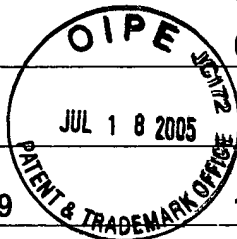
NAIR et al

Filing Date

**February 16, 1999**

C/A.U.

1636



## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**OTHER DOCUMENTS** (including Author, Title, Date, Pertinent pages, etc.)

[illegible]

\*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.